IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WISCONSIN

KATRINA MACPHERRAN,

Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION,

Defendant.

OPINION and ORDER

20-cv-766-jdp

Plaintiff Katrina MacPherran received surgical implantation of a pelvic mesh product manufactured by defendant Boston Scientific Corporation to treat stress urinary incontinence. The surgery did not alleviate the incontinence and MacPherran experienced adverse effects, including severe pain. MacPherran has had three surgeries to remove the mesh product, but her symptoms continue.

MacPherran filed this product liability action against Boston Scientific into a multidistrict litigation (MDL). Her case has been transferred to this court for resolution. Boston Scientific moves for partial summary judgment on some of MacPherran's claims. Of the challenged claims, MacPherran continues to press only one: strict liability for design defect.

The court concludes that Boston Scientific is not entitled to summary judgment on the affirmative defenses raised in its motion. And I conclude that there is a genuine issue of fact about whether there was a reasonable alternative design to Boston Scientific's pelvic mesh product. The motion for summary judgment is denied.

BACKGROUND

A. Undisputed facts

The following facts are undisputed unless noted otherwise.

MacPherran suffered from severe stress urinary incontinence for several years. She had surgery to implant Boston Scientific's pelvic mesh product, Obtryx, on April 9, 2008. Following the surgery, MacPherran's incontinence did not improve, and she developed groin and hip pain, dyspareunia (painful sexual intercourse), and bleeding. MacPherran sought treatment for these adverse symptoms and was referred to a urologist.

Dr. Niall Galloway concluded that implantation of the Obtryx product was the cause of her symptoms. Dkt. 54-12, at 8 (Galloway Dep. 41:1–13). Galloway surgically removed the Obtryx mesh device on January 14, 2014. MacPherran's symptoms did not resolve.

MacPherran underwent two additional surgeries on August 31, 2014 and November 19, 2015. Dr. Shlomo Raz removed additional mesh from MacPherran's tissue, performed vaginal wall reconstruction and repair, and injected Botox at trigger points, among other procedures, to address her symptoms. MacPherran says that she continues to suffer from chronic pelvic and lower back pain, nerve damage, numbness, hip pain, dyspareunia, abdominal pain and headaches, and severe pain while sitting or standing. Dkt. 17, at 8.

B. Procedural history

In 2013, MacPherran filed this product liability action against Boston Scientific into one of seven pelvic mesh multidistrict litigations (MDLs) pending in the United States District Court for the Southern District of West Virginia. *See In re Boston Sci. Corp. Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-md-02326 (S.D.W. Va., Filed Feb. 7, 2012).

Boston Scientific moved for summary judgment in MacPherran's case in May 2019. Dkt. 52. On August 19, 2020, the MDL judge concluded that 16 of the pending MDL cases were ready for transfer to their appropriate jurisdictions, including MacPherran's. Dkt 57.

MacPherran is currently a citizen of Georgia. But her case was transferred here because her Obtryx implantation surgery took place in Janesville, Wisconsin, and she was a citizen of Wisconsin at the time of her surgery. Boston Scientific is a Delaware corporation with its principal place of business in Massachusetts.

ANALYSIS

A. Governing law and summary judgment standard

The court has jurisdiction because the parties are of diverse citizenship and the amount in controversy exceeds $75,000. Because the court's jurisdiction is based on diversity under 28 U.S.C. § 1332, it applies state substantive law and federal procedural law. *Gacek v. Am. Airlines, Inc.*, 614 F.3d 298, 301 (7th Cir. 2010) (citing *Erie R.R. Co. v. Tompkins*, 304 U.S. 64 (1938)).

MacPherran filed this case into the West Virginia MDL, but the parties agree that Wisconsin substantive law applies to her claims because her Obtryx implantation occurred in Wisconsin. S*ee In re Watson Fentanyl Patch Prod. Liab. Litig.*, 977 F. Supp. 2d 885, 888 (N.D. Ill. 2013) (collecting cases for the proposition that "the prevailing rule" when a case is directly filed in the MDL transferee court is to apply the law of "the state where the case originated").

Summary judgment is appropriate if there is no genuine dispute as to any material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). In ruling on a motion for summary judgment, the court views all facts and draws all inferences in the light most favorable to the non-moving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255

(1986). Summary judgment will be granted only if, based on the record as a whole, no rational trier of fact could find for the non-moving party. *Sarver v. Experian Info. Sols.*, 390 F.3d 969, 970 (7th Cir. 2004) (quoting *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586–87 (1986)).

B. Scope of MacPherran's claims

MacPherran originally brought eight claims in the West Virginia MDL: (1) negligence; (2) strict liability for design defect; (3) strict liability for manufacturing defect; (4) strict liability for failure to warn; (5) breach of express warranty; and (6) breach of implied warranty; (7) discovery rule, tolling, and fraudulent concealment; and (8) punitive damages. Dkt. 1. Boston Scientific has not moved for summary judgment on MacPherran's claims for negligence, strict liability for failure to warn, the discovery rule or tolling, or punitive damages, so the case will proceed to trial on those unchallenged claims and issues.

Boston Scientific moved for partial summary judgment on MacPherran's five remaining claims: (1) strict liability for design defect; (2) strict liability for manufacturing defect; (3) breach of express warranty; (4) breach of implied warranty; and (5) fraudulent concealment. Dkt. 52. In response to Boston Scientific's motion for partial summary judgment, MacPherran abandoned her claims for strict liability for manufacturing defect; breach of express warranty; breach of implied warranty, and fraudulent concealment. Dkt. 54. Thus, the only claim at issue on summary judgment is MacPherran's strict liability for design defect claim.

C. Strict liability for defective design

Under Wisconsin law, a strict product liability claim has five elements: (1) the product was defective; (2) the defect rendered the product unreasonably dangerous; (3) the defect existed when the product left the control of the manufacturer; (4) the product reached the

consumer without substantial change; and (5) the defect caused the claimant's damages. Wis. Stat. § 895.047(1). A product is defective in design if the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the manufacturer and the omission of the alternative design renders the product not reasonably safe. *Id.*

Boston Scientific moves for summary judgment on two grounds: (1) the Obtryx sling was cleared by the U.S. Food and Drug Administration, so it is entitled to a presumption that it is not defective; and (2) the use of polypropylene mesh is an inherent characteristic of the Obtryx device. Boston Scientific also argues that MacPherran failed to adduce evidence of a "reasonable alternative design." The court will address each argument in turn.

1. Presumption of non-defectiveness based on FDA clearance

Boston Scientific contends that the Obtryx device is presumed not defective under Wisconsin law because it was cleared through the FDA's 510(k) process in April 2004. Wisconsin's product liability statute, enacted in 2011, establishes a rebuttable presumption that a product is not defective if, at the time of sale, it "complied in material respects with relevant standards, conditions, or specifications adopted or approved by a federal or state law or agency." Wis. Stat. § 895.047(3)(b).

But the FDA 510(k) review process is not the same as full FDA approval or other safety reviews. Wisconsin courts have yet to decide whether a product with 510(k) clearance is entitled to the statutory presumption. The weight of federal cases involving medical devices and Wisconsin's statute or similar state statutes suggests that the 510(k) process does not give rise to § 895.047(3)(b)'s rebuttable presumption.

In *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 755 (S.D.W. Va. 2014), a bellwether case in the West Virginia pelvic mesh MDLs, the court granted the plaintiff's motion in limine to exclude evidence that defendant's mesh product was cleared under the FDA's 510(k) process, relying on *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) and *Riegel v. Medtronic, Inc.*, 552 U.S. 312, (2008). *Lohr* and *Riegel* both held that 510(k) clearance does not preempt state law strict liability claims because the 510(k) process establishes only equivalence to pre-existing devices, not safety to the public. *Lohr*, 518 U.S. at 494; *Riegel*, 552 U.S. at 322-23. *Riegel* characterized 510(k) clearance as "an exemption from safety review." *Riegel*, 552 U.S. at 323. The MDL court concluded that 510(k) clearance was irrelevant in a product liability case and that presenting evidence of it at trial posed a risk of misleading the jury. *Lewis*, 991 F. Supp. 2d at 755.

The MDL court also determined that 510(k) clearance is not relevant to state tort law. *Id.* at 754. Defendants were not entitled Texas's rebuttable presumption of non-defectiveness for products that "complied with mandatory safety standards or regulations adopted and promulgated by the federal government, or an agency of the federal government." *Id.* at 761. *See also In re C.R. Bard, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:11-CV-00195, 2013 WL 3821280, at *7 (S.D.W. Va. July 23, 2013) ("[The] FDA 510(k) process does not go to safety and effectiveness and does not provide any requirements on its own. Basically, it has no . . . operative interaction with state tort laws.").

Federal courts applying Wisconsin law have also concluded that § 895.047(3)(b)'s rebuttable presumption does not extend to medical devices cleared through the FDA's 510(k) process. *Hall v. Bos. Sci. Corp.*, No. 2:12-CV-08186, 2015 WL 874888, at *2 (S.D.W. Va. Feb. 27, 2015) involved Boston Scientific's Obtryx device. The court concluded that because

Wisconsin's product liability statute concerns whether a defect makes a product "unreasonably dangerous," and the Supreme Court has held that 510(k) clearance does not speak to a product's safety, the presumption did not apply. *Id.* (citations omitted). Similarly, *In re Bard IVC Filters Prod. Liab. Litig.*, No. CV-16-00893-PHX-DGC, 2018 WL 3586404, at *6 (D. Ariz. July 26, 2018), concluded that Wisconsin's rebuttable presumption did not apply to an intravenous medical device that had received 510(k) clearance. The court reasoned that a product is only defective if it is "not reasonably safe," but that 510(k) clearance provided no assurance of safety because the process is focused on equivalence. *Id.* at *6-7. *See also Hanson v. Bos. Sci. Corp.*, No. 2:13-CV-10653, 2016 WL 1448868, at *3 (S.D.W. Va. Apr. 12, 2016); *Williams v. Bos. Sci. Corp.*, No. 2:12-CV-02052, 2016 WL 1448860, at *3 (S.D.W. Va. Apr. 12, 2016).

The reasoning of these cases is persuasive, particularly in light of the holding in *Riegel* that 510(k) clearance is not a safety review, but an exemption from safety review. Accordingly, the court concludes that Boston Scientific's Obtryx device is not entitled to the statutory presumption that it is not defective. Boston Scientific is not entitled to summary judgment on this issue.

2. Inherent characteristic defense

Boston Scientific contends that MacPherran cannot base her design defect claim on the use of polypropylene mesh because polypropylene mesh is an inherent characteristic of the Obtryx device. Dkt. 52, at 6. Wisconsin's product liability statute codifies an affirmative defense base on the inherent characteristics of the product: "the court shall dismiss the claimant's action under this section if the damage was caused by an inherent characteristic of the product that would be recognized by an ordinary person with ordinary knowledge common

to the community that uses or consumes the product." Wis. Stat. § 895.047(3)(d). The defense was also available under Wisconsin common law. In *Godoy ex rel. Gramling v. E.I. du Pont de Nemours & Co.*, 2009 WI 78, ¶ 37, 319 Wis. 2d 91, 115, 768 N.W.2d 674, 685, the Wisconsin Supreme Court held that a claim for defective design cannot be maintained where a product's alleged defect is the presence of an ingredient that is inherent to the product itself. *Godoy* involved a design defect claim against manufacturers of white lead carbonate pigment, which was used in lead paint. *Id.* at ¶ 26. The pigment's alleged design defect was the presence of lead. *Id*. The court concluded that the presence of lead cannot be a defective design feature because "without lead, there can be no white lead carbonate pigment." *Id.* at ¶ 37.

Boston Scientific attempts to draw a parallel to *Godoy* by characterizing the Obtryx device as a polypropylene mesh product. And, so the argument goes, polypropylene cannot be a design defect of polypropylene mesh because polypropylene is the very characteristic that makes the product what it is. The court is not persuaded. Under Boston Scientific's view, this affirmative defense becomes a semantic game in which the defendant can prevail by including the dangerous ingredient in the name of the product. If MacPherran's claim were against the manufacturer of the polypropylene mesh, and she alleged that the mesh was defective because it contained polypropylene, the inherent characteristic defense might apply. But that is not the case here, where Boston Scientific chose to include the dangerous component.

MacPherran fairly identifies the Obtryx device as a pelvic mesh product. As the court explains below in its discussion of reasonable alternative designs, MacPherran has adduced evidence that a pelvic mesh product can be made with a variety of mesh styles, or that it need not be made with polypropylene at all. *See* Dkt. 54 and Dkt. 92. Because pelvic mesh products can be made with different types of mesh, use of a non-polypropylene mesh would not turn

the product into something else. Boston Scientific is not entitled to summary judgment on the "inherent characteristic" affirmative defense under § 895.047(3)(d) or Wisconsin common law.

3. Evidence of reasonable alternative designs

To prevail on her strict liability for design defect claim, MacPherran must show that the "foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the manufacturer and the omission of the alternative design renders the product not reasonably safe." Wis. Stat. § 895.047(1)(a). Boston Scientific contends that MacPherran has not adduced any evidence of a reasonable alternative design to the Obtryx mesh sling. Dkt. 78, at 8. If true, this would be fatal to MacPherran's strict liability claim. But Boston Scientific raised this argument for the first time in its reply, so the court asked MacPherran for her response. Dkt. 91.

In response to the court's request, MacPherran cited the following alternatives to the Obtryx sling's design: "lighter-weight/large pore grafts; mesh slings constructed from native tissue, cadaver tissue, bovine or porcine; as well as midurethral slings implanted by retropubic approach." Dkt. 92. MacPherran adduces expert testimony to show that at least some of these alternatives could have reduced the risk of harm that the Obtryx device posed to patients. For example, Dr. Jerry G. Blaivas's expert report states that pelvic sling systems manufactured from biologic mesh or that use native tissue carry a lower risk of complications than synthetic slings. Dkt. 92-5, at 3–4. In a deposition, Dr. Bruce Rosenzweig testified that mesh with higher density and smaller pores tends to produce more erosion and tissue destruction, and mesh products with varying density and pore size are available. Dkt. 92-8 (Rosenzweig Dep. 60:13–61:24).

The expert report of Dr. Peggy Pence, moreover, lists several factors that affect the human body's inflammatory response to mesh implantation: the nature of the implant material, including chemical and physical structure, the amount of material and surface of the contact area with the patient's tissue, and the filament and pore size. Dkt. 92-2. The report points to several studies in which researchers tested degradation of several types of mesh products implanted in dogs and humans. The reports concluded that mesh with lower polypropylene content produced less severe inflammatory responses. *Id.* at 31–33. Another study found that polyester mesh resulted in less tissue damage than polypropylene mesh. *Id.* at 33.

MacPherran's expert evidence is sufficient to create a genuine dispute of material fact whether a safer alternative design to the Obtryx device was available to Boston Scientific. Summary judgment on this basis is denied.

ORDER

IT IS ORDERED that: defendant Boston Scientific's motion for summary judgment, Dkt. 52, is DENIED.

Entered December 2, 2020.

BY THE COURT:

/s/

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JAMES D. PETERSON
District Judge